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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 18, 2006

File # 07-NWJ-05

Mr. Lance Collins
President and CEO
FUZE Beverages, LLC
140 Sylvan Avenue
Englewood Cliffs, NJ 07632

Dear Mr. Collins:

On July 31 and August 2, 2006, the Food and Drug Administration (FDA) conducted an inspection of [redacted], located at [redacted]. During that inspection, we determined that [redacted] manufactures FUZE® Healthy Infuzions products under contract to your firm, which markets these products. We further determined that your firm is solely responsible for the labeling of FUZE® Healthy Infuzions products.

During the inspection, our investigator collected the labeling for several of your FUZE® Healthy Infuzions products. FDA reviewed the labels for your FUZE® Healthy Infuzions refresh™ (Banana Colada), FUZE® Healthy Infuzions Green Tea with Honey and Ginseng, FUZE® Healthy Infuzions Diet Green Tea (Orange Ginger Green Tea), FUZE® Healthy Infuzions ENERGIZE (Mojo Mango), and FUZE® Healthy Infuzions focus (Orange Mango) products. Our review revealed that the above products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC § 321(g)(1)(B)]. The marketing of these products with such claims violates the Act. In addition, FUZE® Healthy Infuzions ENERGIZE (Mojo Mango) and FUZE® Healthy Infuzions Green Tea with Honey and Ginseng are misbranded foods under section 403 of the Act, Title 21 of the United States

States Code 343 [21 USC § 343]. You can find the Act and FDA's regulations through links on FDA's Internet web site at http://www.fda.gov.

The violations are as follows:

- Your Fuze® Healthy Infuzions refresh™ (Banana Colada), Fuze® Healthy Infuzions Green Tea with Honey and Ginseng, FUZE® Healthy Infuzions Diet Green Tea (Orange Ginger Green Tea), Fuze® Healthy Infuzions ENERGIZE (Mojo Mango), and Fuze® Healthy Infuzions focus (Orange Mango) products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Act [21 USC § 321(g)(1)(B)]. The therapeutic claims in your labeling establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

  Examples of label claims that promote your products for use as drugs include:

  Fuze® Healthy Infuzions refresh™ (Banana Colada), Fuze® Healthy Infuzions ENERGIZE (Mojo Mango), and Fuze® Healthy Infuzions focus (Orange Mango):

  - Vitamin B_3: "Known to . . . reduce the cholesterol level in the blood."

  FUZE® Healthy Infuzions Green Tea with Honey and Ginseng and FUZE® Healthy Infuzions Diet Green Tea (Orange Ginger Green Tea):

  - Polyphenols: "[A]ssociated with reduced risk of developing cardiovascular disease and certain cancers."

  Furthermore, these products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are "new drugs" under section 201(p) of the Act [21 USC § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 USC § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

- As foods, your FUZE® Healthy Infuzions ENERGIZE (Mojo Mango) and Green Tea with Honey and Ginseng products are misbranded within the meaning of section 403(u) of the Act [21 USC § 343(u)] in that they purport to contain ginseng, but the purported ginseng ingredient is not from a plant classified within the genus Panax. Section 403(u) of the Act, added by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), provides that the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or

herbal ingredient derived from a plant classified within the genus Panax. Your products contain an ingredient identified as Siberian Ginseng (*Eleutherococcus senticosus*). That ingredient may not be declared under a name that includes the term "ginseng" because it is not from the genus Panax.

We may take further action without notice if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

This letter may not list all violations in your products and their labeling. You are responsible for ensuring that your facility operates in compliance with the Act, the Current Good Manufacturing Practice regulations and FDA's food labeling regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

In addition to the violations described above, FDA has the following comments concerning the labeling of your products:

- The ingredient statement of your Fuze® Healthy Infuzions Diet Green Tea (Orange Ginger Green Tea) product declares "natural orange ginger green tea flavor" in addition to green tea solids and white tea solids. Based on the statement of identity for this beverage, you are representing green tea as its characterizing flavor. We remind you that in accordance with 21 CFR 101.22(i)(1)(i), if the amount of green tea solids is insufficient to independently characterize the beverage, your product label must identify this beverage as "green tea flavored" or "natural green tea flavored" in the statement of identity.

- Your Fuze® Healthy Infuzions Diet Green Tea (Orange Ginger Green Tea), Fuze® Healthy Infuzions ENERGIZE (Mojo Mango), and Fuze® Healthy Infuzions focus (Orange Mango) product labels do not declare *trans* fat in the Nutrition Facts panels. Regulations requiring the declaration of *trans* fat went into effect on January 1, 2006 (see 21 CFR 101.9(c)(2)(ii); 68 FR 41433). You should review all of your product labels to ensure they comply with these regulations. For additional information on trans fat labeling, go to http://www.cfsan.fda.gov/~dms/lab-cat.html#transfat.

- Your Fuze® Healthy Infusions products discussed in the violation section of this letter are labeled with a dietary supplement disclaimer statement. Because these products are conventional foods, not dietary supplements (see definition of "dietary supplement" in 21 USC § 321(ff)), their labels should not include this disclaimer.

- The statements of identity on the labels of your FUZE® Healthy Infuzions refresh™ (Banana Colada), ENERGIZE (Mojo Mango), and focus (Orange Mango) products do not accurately identify these products in that they lack an appropriately descriptive term such as "beverage" or "drink" to describe the basic nature of the food (see 21 CFR 101.3(b) and 102.5).

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District